Sustaining Members •

University of California California Institute of Technology California State University Stanford University University of Southern California California Community Colleges



December 14, 2004

Mr. Robert Klein President Klein Financial Corporation 550 California Ave, Ste 330 Palo Alto, CA 94306

Dear Mr. Klein:

The success of Proposition 71 and the formation of the California Institute of Regenerative Medicine (CIRM) mark an important moment in the history of public funding of research. The opportunity for California to be the leader in adult and embryonic stem cell research is exciting, yet among the challenges facing the members of the Independent Citizens Oversight Committee (ICOC) is the establishment of best practices to ensure that public resources are wisely distributed and administered.

The California Council on Science and Technology (CCST) would like to assist the ICOC on a number of science and technology policy issues surrounding stem cell research that may impact California's life-sciences research and technical workforce, economy and educational system. In particular, CCST could help determine "public interest" value of the research program and assist in deciding strategies for intellectual property policy.

In 1988, the California state government put into place CCST, a non-partisan, impartial, not-for-profit organization designed to offer expert advice to the state and provide solutions to science and technology related public policy issues. CCST's current academic members are the University of California, the California State University System, the California Community Colleges, California Institute of Technology, Stanford University, and the University of Southern California. CCST also works closely with the National Academies. In addition, CCST forged a closer collaboration with the National Academies in 2004 so as to enhance its capacity to seek and utilize scientific and technical expertise to provide timely and relevant advice on important policy issues impacting the state.

Throughout its history, CCST has had a proven track record of identifying the public benefit of research. In particular, we have conducted sound analyses using metrics that enable objective valuation of the impacts of research. One recent example is the series of studies, over the past four years, of the impact of the state's largest energy research program. In 2003, the California Energy Commission (CEC) requested CCST convene a new Independent Review Panel (IRP) to evaluate the Public Interest Energy Research

Program (PIER). Because the Preliminary and Final reports produced by CCST in 2000 and 2001 as part of the first PIER review provided effective guidance to PIER program management for the last two years, the CEC contracted with CCST to conduct the second IRP process and produce a new set of reports in 2004 and 2005. If requested, CCST could perform a similar function for the CIRM, and thus provide independent, evidence-based assessments of the benefits accruing to the public and the state by their investment in stem cell research.

A second important issue that the ICOC will face early on is intellectual property (IP). Development of innovative technologies is fundamental to the California economy; however, lack of understanding about the research enterprise and technology transfer, as well as lack of clarity concerning the role of the State government, if any, in developing IP into marketable products make it difficult for the State to design an effective IP policy. Currently, the state of California does not have a uniform policy of a consistent set of practices stemming from a clearly stated set of goals in its approach to the management of IP created under state contracts, grants, agreements.

In order to better prepare state policymakers to consider an IP policy framework appropriate for the state of California, the Legislature through ACR 252 has requested that CCST conduct an analysis on how to treat the intellectual property developed under state agreements in such a way as to most effectively meet the needs of the state. In the Federal arena, this was accomplished by the Federal Bayh-Dole Act (Public Law 96-517) that allows technology-based small businesses and nonprofit research institutions to own patents arising out of federally sponsored research, provided that such inventions are diligently developed into goods and services that ultimately benefit the public. The goal of the CCST effort is to produce a report with guidelines and principles that will not only meet the needs of the state, but will also allow uniformity in the way the State addresses IP created under state contracts and agreements. This project will be conducted by a Study Group of experts in IP, and is scheduled to be completed by December 2005. It will address the following questions:

- What is the state trying to maximize or optimize through its treatment of IP created in state-funded research?
- What are the appropriate trade-offs among these goals and what timeframes are involved?
- Strategically, how do existing practices affect these objectives and how can recommended approaches bias the trade-offs towards achieving the goal?
- Tactically, what mechanisms or procedures could be established to maximize the intended outcomes and to minimize non-productive activities in IP management?
- Which remedies should be embodied in law, in recommended best practices, or a combination of both?

The timeliness of the beginning of this project works to the ICOC's and CIRM's advantage. CCST invites the ICOC to appoint up to two members or designees on

behalf of ICOC to join the Study Group and participate in its deliberations. Such involvement by ICOC will enable a timely flow of information between the Study Group and CIRM as it works quickly to establish its policies and procedures, and will ensure that all key stakeholders are part of the study process at this critical time.

We look forward to talking with you at your earliest convenience and to working with ICOC on this and other issues that will arise in the years to come.

Sincerely,

C. Judson King

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Executive Director

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